REMARKS

Upon entry of the Amendment, claims 6 and 9-10 will be pending. Claim 6 is amended to incorporate the subject matter of claim 7. Accordingly, claim 7 is canceled without prejudice or disclaimer. Claims 9 and 10 are amended to correct typographical errors.

No new matter is added. Entry of the Amendment is respectfully requested.

I. Claim Rejections under 35 U.S.C. § 103

Claims 6-7, and 9-10 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gardiner et at. (1998, Development of a probiotic cheddar cheese containing human -derived Lactobacillus paracasei strains; hereinafter "Gardiner") in view of DE 1955833 (hereinafter "R2") and Kimura et al. (EP 1 112 692 Al, hereinafter "Kimura").

Claims 6-7 and 9-10 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over R2, Kimura et al. (EP 1 112 692 Al, hereinafter "Kimura"), further in view of Germond et al. (WO 0188150, hereinafter "Germond").

Applicants note that all the references were cited in the previous Action, and the Office reiterates in general the same rationale as was set forth in the Office Actions of August 22, 2007, April 8, 2008 and March 25, 2009

To the extent that the cited references and the rejections are the same or substantially the same, Applicants reiterate herein, by incorporation by reference, the arguments presented in the previously submitted Amendments and Responses.

Applicants respectfully traverse the rejection and submit the followings.

"timing of addition of yeast extract"

Independent claim 6 recites that the process further comprises adding an yeast extract to the raw milk at the same time or after adding the lactic acid bacteria starter to the raw milk in

step (1), and before formation of the curd in step (2).

As described in Fig. 3, as well as testified by Mr. Mitsuro Matsuo in the concurrently filed Rule 132 Declaration, when cheese is produced by adding yeast extract to milk component before formation of curd, *L. gasseri* increases during one month of preservation and keeps a high bacterial count. On the other hand, when cheese is produced without adding yeast extract, *L. gasseri* dose not increase during preservation of cheese and the bacterial count decreases with lapse of time of preservation.

Applicants respectfully disagree with the Examiner's characterization of R2.

R2 is cited by the Examiner as assertedly disclosing a process where cheese of all types with improved storage life, higher yield and improved aroma are obtained by replacing or supplementing conventional cheese cultures with Bifidus bacteria and preferably *adding growth activators such as yeast extract* to the milk (Abstract).

It is noted that on pages 7-8 of the Action, the Examiner takes the position that since R2 discloses that milk is mixed with 1.5% yeast autolyzate or yeast extract and sterilized, therefore, it is clear yeast extract is being added to raw milk.

Applicants disagree.

In particular, paragraph a) in Example 1 of R2 describes a process wherein a starter of *Lactobacillus bifidus* is produced by pre-culture. As evidenced, sterilization was carried out after mixing milk with 1.5 % yeast autolyzate or yeast extract. Indeed, Example 1 of R2 is an example wherein culture medium (milk) for incubation of starter includes yeast extract. Example 1 of R2 is not an example of adding yeast extract in production of cheese and is not addition of yeast extract to cheese.

Applicants include herewith the translation of paragraph a) in Example 1 of R2 to facilitate the Examiner's review.

> a) Nonfermentable rennet curd
> Culture in the level in a laboratory:
> To milk, 1.5% yeast extract autolyzate or yeast extract was added and sterilized. After cooling down to 35-45 °C, axenic *Lactobacillus bifidus* was inoculated (Please see patent application A.Z. p 19 46 661.6, filed on September 15, 1969 with regard to the production of axenic *Lactobacillus bifidus.),* followed by incubation in incubater having temperature of 35-45 °C to allow the liquid to be condensed. At this point, pH becomes 4.3 to 4.8. Necessary time is 2 or 4 hours depending on the amount of inoculation of *Lactobacillus bifidus.*

R2 discloses adding yeast extract as growth activators; however, contrary to the Examiner's assertion, R2 does not disclose or recognize the addition of an yeast extract before formation of the curd and after incubation of the lactic acid bacteria starter so as to allow L. gasseri grow and survive in cheese dominantly over lactic acid bacteria for cheese.

R2 does not disclose or teach adding an yeast extract to the raw milk at the same time or after adding the lactic acid bacteria starter to the raw milk, and before formation of the curd, as required in present claim 6.

In addition, as testified by Mr. Mitsuro Matsuo in the concurrently filed Rule 132 Declaration, Test Example 2 of the instant application (at pages 29-30 and Fig. 7) relates to studies of growth of various lactic acid bacteria strains under acid condition, and the test result (as shown in Fig. 7) clearly demonstrates that each *Lactobacillus* strains has different growth rate and survival rate under the same acid condition. The Examiner's assertion lacks scientific grounds because, as explained by Mr. Mitsuro Matsuo in the concurrently filed Rule 132 Declaration, it is not reasonable to assume all *Lactobacillus* strains are expected to have same growth rate and survival rate overtime when incorporated into cheese, and it is not reasonable to

assume that L. paracasei and *Lactobacillus gasseri* strains are interchangeable. See also Gardiner.

In view of the forgoing, contrary to the Examiner's assertion, R2 does not disclose or teach adding an yeast extract to the raw milk at the same time or after adding the lactic acid bacteria starter to the raw milk, and before formation of the curd, as required by claim 6.

"incubation of the curd"

Furthermore, claim 6, as amended, recites that the incubation of the curd is carried out without cooling the curd after molding and pressing.

The instant specification discloses at page 14, second paragraph, that the survival ratio of *L. gasseri* in the natural cheese can be improved by incubating the curd after the molding and pressing (i.e., formation of the pressed pieces of curd). The incubation is preferably carried out, for example, without cooling immediately after the molding and pressing. Furthermore, the incubation is carried out at 20 to 35°C for 16 to 26 hours, preferably at 22 to 28°C for 19 to 24 hours.

It is respectfully submitted that the conventional methods of making cheese would require immediately cooling after the molding and pressing. Applicants submit herewith a copy of a publication entitled Cheese Chemistry, Physics and Microbiology, Volume 2, Third Edition, wherein at page 106 of the publication, it describes normal production method of Gouda cheese. Among the production steps, the brining step corresponds to cooling step. Further, on page 113 of the publication, at the relevant portion regarding the brining step, it describes that temperature is cooled down to be 15 °C.

Applicants respectfully submit that "the curd is incubated without being cooled after molding and pressing", as recited in present claim 6, is an unexpected step which is critical to

attain the desired viable counts of the L. gasseri.

According to the method defined in the present claim 6, the "incubation" of the curd is conducted on the curd obtained after removing whey, molding and pressing, and forming pieces of the curd kept at 20 to 35 °C for 16 to 26 hours.

In contrast, in Gardiner, the cheese is kept for one night outside of a room during pressing and molding in process of removing whey in cheese production, which is different from the "incubation" of the present application.

As testified by Mr. Mitsuro Matsuo in the concurrently filed Rule 132 Declaration, it is respectfully submitted that increasing the viable count of a certain microorganism to a target level by controlling the temperature and time of incubation of a curd that comprise the certain microorganism is different from keeping a cheese outside of a room.

In the present application, "incubation" is carried out for increasing viable count. It is different from "aging" and "maturation" which are process in usual cheese production for improving taste and flavor by hydrolysis of protein by enzymes which are excreted from dead microorganism etc.

Further, as explained by Mr. Mitsuro Matsuo in the concurrently filed Rule 132 Declaration, when curd after molding and pressing is incubated without cooling, L. gasseri increases during one month of preservation and keep high bacterial count. On the other hand, when curd after molding and pressing is incubated with cooling, *L. gasseri* dose not increase during preservation of cheese and a decrease in the bacterial count due to elapse of time of preservation.

None of the cited references disclose or teach that the curd is incubated without being cooled after molding and pressing. The advantageous effects of the claimed process for producing a natural cheese was not predictable.

Thus, it is respectfully submitted that Gardiner in view of R2, Kimura and/or Germond, does not disclose or render obvious the claimed process for producing a natural cheese, as recited in present claim 6.

"viable cell count overtime"

Claim 6 also recites that the natural cheese comprises the lactic acid bacterium belonging to *Lactobacillus gasseri* having a disinfection potency against *Helicobacter pylori,* wherein the natural cheese has a viable cell count of *Lactobacillus gasseri* in the number of 10^7 cfu/g or more when preserved at a temperature of 10°C or less for 6 months.

As shown in Fig. 3 of the instant specification, as well as testified by Mr. Mitsuro Matsuo in the concurrently filed Rule 132 Declaration, it is difficult to keep necessary microorganisms at a desired level overtime. Fig. 3 of the instant specification relates to studies of bacterial count changes in *L. gasseri*-enriched gouda cheese.

Further, as explained by Mr. Mitsuro Matsuo in the concurrently filed Rule 132 Declaration, Applicants respectfully submit that microorganisms in cheese usually become dead microorganisms during process of improving taste and flavor in "aging" and "maturation" by hydrolysis of protein by enzymes which are excreted from dead microorganism. When plural microorganisms exist in cheese, the person skilled in the art cannot know which microorganism will survive. Therefore, the present invention wherein target microorganism can survive in object amount or more is novel and unobvious.

Conclusion

In view of the amendment to claim 6 and the foregoing remarks, Applicants respectfully submit that the present claims are not obvious over Gardiner, in view of R2, Kimura and/or Germond. Reconsideration and withdrawal of the present § 103(a) rejections of claims 6 and 9-10 are respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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